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PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	David Philip Lane
Appl. No.	:	09/403,440
Filed	:	January 19, 2000
For	:	MATERIALS AND METHODS RELATING TO INHIBITING THE INTERACTION OF p53 AND mdm2
Examiner	:	Davis, Minh Tam B

Group Art Unit 1642

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: United States Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, on

December 10, 2002
(Date)

Ginger R. Dreger, Reg. No. 33,055

RESPONSE TO RESTRICTION REQUIREMENT

United States Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Dear Sir:

This is in response to the Office Action mailed on September 10, 2002 in connection with the above-identified patent application (Paper No. 15), setting a one-month term. Accompanying the present response is a request for a two-month extension of time setting the new term to December 10, 2002.

The Examiner acknowledged applicant's election of the Group I claims (Claims 1-9 and 11) in response to the prior restriction requirement communicated in the Office Action mailed on March 30, 2001, but found that "[a]fter review and reconsideration, groups I-II require further restriction." In particular, applicants were requested to elect either prevention or treatment for examination in the present application, "because when a disease is treated, if does not necessarily mean that said disease could be prevented." Applicants were further advised that if a group having species requirement is elected, "a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon."

Since the Office Action indicates that claims 1-27 are pending, it is assumed that Applicants' election of the Group I claims has not been entered, and the present Office Action should be considered to incorporate all requirements initially communicated in the Office Action mailed on March 30, 2001, and the additional requirement to elect either prevention or treatment within the elected Group.

In order to be responsive to the restriction requirement, Applicants hereby elect the claims of Group I (claims 1-9, and 11 drawn to a method of *treating* a condition comprising disrupting the binding of a human p53 and mdm2), the species of a peptide having an amino acid sequence corresponding to human p53, and the further species of cancer as the condition to be treated, with traverse. Claims 1-6, 8, and 11 read on the elected species.

Since the Examiner regrettably failed to address Applicants' grounds for traversal set forth in the Amendment mailed on June 11, 2001, Applicants hereby repeat and request consideration of the same arguments.

It is submitted that the restriction/election requirement is based on an improper interpretation of PCT Rules 13.1-13.3 and should be withdrawn. According to PCT Rule 13.1 *"The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept."* (Emphasis added.) PCT Rule 13.2 provides: *"Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."* (Emphasis added.) Finally, according to PCT Rule 13.3, *"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."*

The "single general inventive concept" underlying the present invention is the realization that mdm2 suppresses p53 not only in cells in which mdm2 is overexpressed, but also in cells in which it is not. All aspects of the invention share this inventive concept, as they all relate to reducing binding between mdm2 and p53, whether by disrupting that binding or by reducing the amount of mdm2 available to participate in binding. This is the contribution that each of the

claimed inventions, considered as a whole, makes over the prior art, and this is why the International Preliminary Examining Authority, applying the same PCT Rules, found that the entire claim set met PCT unity requirements.

Although M.P.E.P. Section 1850 gives examiners a large degree of latitude in assessing the unity of an invention, dissection of a claim based upon the action mechanism by which an intended result is achieved, as the Examiner has done by treating the disruption of p53 and mdm2 binding and the inhibition of mdm2 production as separate and distinct inventions, is believed to be at odds with well established practice of the USPTO, even as it applies to non-PCT originating, national U.S. applications. Accordingly, as a minimum, even under the strictest standards Groups I and II, Groups III and IV, and Groups V and VI should be examined in one application.

The additional requirement to restrict the claims to either treatment or prevention is believed to be misplaced and should not stand for the same reasons.

The election of species requirement is even less sustainable. The Examiner seems to have overlooked that claim 5 depends on claim 3, and therefore, concerns a peptide having an amino acid sequence corresponding to human p53 and additionally including an FxxxW (now referred to as FXaaXaaXaaW) motif. Accordingly, both peptides share the amino acid sequence of human p53, and should not be viewed as distinct species. Similarly, viewing a peptide and a fusion peptide as distinct species is contrary to settled practice. The same applies to treating microinjection and transport as distinct species, "because they work by different mechanisms."

In view of the foregoing arguments, applicant requests the reconsideration and withdrawal of the restriction and election of species requirements, and the examination of all claims pending in this application.

The Examiner is respectfully requested to reconsider and withdraw the restriction and election of species requirements in view of the foregoing arguments. Should any part of the restriction and election of species requirements be maintained, as a minimum, the Examiner is requested to address Applicants arguments, pointing out why the restriction/election of species requirements do not contravene PCT Rules 13.1-13.3, and well established practice of the United States Patent and Trademark Office.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 10, 2002

By: _____

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